

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-25 and 27-31 are pending in the application. Claims 1, 2, 5, 16, 19, 22 and 23 have been amended to address the formal matters raised in the outstanding Official Action. Claims 3, 6, 7, 11-14, and 27-29 have been withdrawn from consideration pursuant to 37 CFR 1.142(b). However, applicant maintains that the restriction of these claims is improper for the reasons set forth in the amendments of March 15, 2006 and April 19, 2006. Accordingly, applicant respectfully requests the rejoinder of the withdrawn claims.

The outstanding Official Action objected to the abstract. Accordingly, applicant provides herewith a revised abstract.

Claims 1, 2, 4, 5, 8-10, 15-24 and 30-31 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the enablement requirement. This rejection is respectfully traversed.

In imposing the rejection, the Official Action contends that it is unclear how to process "status-characterizing information", what constitutes "identity data", and how to determine the parameters of a "deferred-use protocol".

At page 5, lines 15-20, the specification explains how to determine a subject's identity data and how status-characterizing information is processed as follows:

"The status-characterizing information is processed to determine a subject's identity data, for example by extracting from said status-characterizing information relevant data on personal immunity history and data. The subject's identity data may include immunity-related data, historical and clinical data on previous diseases, treatments and therapeutic protocols experienced by said subject."

The specification also describes the use of an expert system for generating the subject's "identity data" at page 14, line 26 to page 15, line 2:

"The status-characterizing information corresponding to a subject are entered into the expert system, in the form of biological items to which a set of rules stored in a knowledge base is applied to generate the subject's identity data.

For example, it can be referred to US patent 5,694,950 disclosing a method and system for use in treating a patient with immunosuppressants using whole blood level criteria to prevent an adverse immune response, which implements an expert system."

Thus, one skilled in the art would understand how to determine identity data from status-characterizing information. Indeed, it is common in medical activities to collect and process patient's identity data, such biological or physical tests, previous diagnosis and therapeutic data.

Step (iv) identified by the Official Action and is directed to determining parameters of a deferred-use protocol of batches of immunocompetent cells. This is achieved by processing

the successively collected subject's identity data. In this regard, the specification teaches,

Parameters of a protocol of re-use are determined by requesting identity data from the cell management database and processing said identity data to determine for example optimal ratio between lymphocytes T4 and T8 for re-injection (see page 14, lines 5-8).

For example, a deferred-use protocol may comprise as a way of non-limitative example, an optimal time schedule indicating the proposed dates for deferred use depending on collected personal parameters and therapeutic indications for re-use, and biological and technical indications required for cell processing before re-use (see page 16, lines 5-8).

In view of the above, one skilled in the art would have no difficulty in implementing this parameter-determination step, by using expert systems and information systems. The processed data are accessible to any skilled professional in the field of medicine and human or animal biology.

Therefore, by merely accessing protocols for autologous cell use and implementing expert system techniques for producing deferred-use parameters from identity data, one skilled in the art would plainly be able to practice the claimed invention.

As to the ZHANG et al. and SHORTLIFFE et al. publications cited by the outstanding Official Action on pages 4 and 5, neither publication relates to a method or system for managing batches of immunocompetent cells collected from human or animal subjects for deferred use.

The Examiner is respectfully reminded that it is a well founded principle that any assertion by the Patent Office that

the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed.

As a matter of law, the expressed teaching of the patent specification cannot be controverted by mere speculation and unsupported assertions on the part of the Patent Office. As stated by the Court of Customs and Patent Appeals in the case of *In re Dinh-Nguyen and Stanhagen*, 181 USPQ 46 (CCPA 1974):

Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. 181 USPQ at 47.

Such a standard must be applied with great care when the Examiner's conjecture is contrary to the teachings of the specification. As neither publication relates to a method or system for managing batches of immunocompetent cells collected from human or animal subjects for deferred use, it is believed that the publication do not qualify as evidence showing that the present disclosure is not enabling for the claimed invention.

Thus, in view of the above, applicant respectfully requests that the enablement rejection be withdrawn.

Claims 1, 2, 4, 5, 8-10, 15-24 and 30-31 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention. Applicant believes that the present amendment overcomes this rejection.

As to claim 1, claim 1 has been amended so that phrases and terms "enhancing", "effected", "upon a request for re-use", and "storing, all along said steps" are no longer recited. However, applicant does not disclaim that improving or enhancing the recited "personal library" step. Rather, claim 1 recites an active step of constituting from collected batches a personal library of immunocompetent cells, wherein the personal library contains a sum of immunity information stored in the walls of the collected immunocompetent cells from one or more batches of immunocompetent cells. Thus, personal library is improved or enhanced in that the personal library contains a sum of immunity information stored in the walls of the collected immunocompetent cells from one or more batches of immunocompetent cells. In this regard, applicant does not disclaim "improving" or "enhancing" the personal library in any of the claims.

While applicant acknowledges that claim 1 is directed to a "method for managing batches of immunocompetent cells," each of the steps is directed to managing batches of immunocompetent cells. In this regard, applicant believes that the preamble is perfectly consistent with the recitations set forth in the claim. Furthermore, it is believed that claim 1 is broad in terms of what batches can be reused at some future point, or for a particular medical condition.

As noted above, claims 2, 5, 16, 19, 22 and 23 have also been amended to avoid the formal matters raised in the outstanding Official Action.

In that the claims have only been amended to address formal matters, applicant believes that the changes to the claims are non-narrowing in scope.


Applicant believes that all of the claims under consideration are definite to one skilled in the art.

In view of the above, applicant believes that the present application is in condition for allowance at the time of the next Official Action.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item:

- new Abstract of the Disclosure